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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,951	08/28/2003	Jia-He Li	70003.0002USD1	6259
30678	7590	07/21/2004	EXAMINER	
CONNOLLY BOVE LODGE & HUTZ LLP SUITE 800 1990 M STREET NW WASHINGTON, DC 20036-3425			REYES, HECTOR M	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,951

Applicant(s)

LI ET AL.

Examiner

Hector M Reyes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-115 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-118 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Restriction Request

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11 in part, drawn to nonheterocyclic derivatives of formula I including its salts, and its pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.
- II. Claims 1-11 in part, drawn to heterocyclic derivatives of formula I including its salts, and pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.
- III. Claims 12- 14 in part, drawn to method of using compounds embraced by formula I or its salts as described in the said claims. This group may be subjected to further restriction. A single disclosed specie is requested for search purposes.
- IV. Claims 1-11 in part, and claims 12-14 drawn to pharmaceutically acceptable prodrug or pharmaceutically active metabolites derivatives of formula I or its corresponding salts, and its pharmaceutical compositions, and methods of using the same, classified in multiple classes and

subclasses. This group may be subjected to further restriction. A single disclosed specie is requested for search purpose.

- V. Claims 15-25 in part, drawn to nonheterocyclic derivatives of formula II including its salts, and its pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.
- VI. Claims 15-25 in part, drawn to heterocyclic derivatives of formula II including its salts, and pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.
- VII. Claims 26-32 in part, drawn to method of using compounds embraced by formula II or its salts as described in the said claims. This group may be subjected to further restriction. A single disclosed specie is requested for search purposes.
- VIII. Claims 15-25 in part, and claims 26-32 drawn to pharmaceutically acceptable prodrug or pharmaceutically active metabolites derivatives of formula II or its corresponding salts, and its pharmaceutical compositions, and methods of using the same, classified in multiple classes and

subclasses. This group may be subjected to further restriction. A single disclosed specie is requested for search purpose.

- XI. Claims 33-43 in part, drawn to nonheterocyclic derivatives of formula III including its salts, and its pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.
- X. Claims 33-43 in part, drawn to heterocyclic derivatives of formula III including its salts, and pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.
- XI. Claims 44-46 in part, drawn to method of using compounds embraced by formula III or its salts as described in the said claims. This group may be subjected to further restriction. A single disclosed specie is requested for search purposes.
- XII. Claims 33-43 in part, and claims 44-46 drawn to pharmaceutically acceptable prodrug or pharmaceutically active metabolites derivatives of formula III or its corresponding salts, and its pharmaceutical compositions, and methods of using the same, classified in multiple classes and

subclasses. This group may be subjected to further restriction. A single disclosed specie is requested for search purpose.

- XIII. Claims 47-57 in part, drawn to nonheterocyclic derivatives of formula IV including its salts, and its pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.
- XIV. Claims 47-57 in part, drawn to heterocyclic derivatives of formula IV including its salts, and pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.
- XV. Claims 58-60 in part, drawn to method of using compounds embraced by formula IV or its salts as described in the said claims. This group may be subjected to further restriction. A single disclosed specie is requested for search purposes.
- XVI. Claims 47-57 in part, and claims 58-60 drawn to pharmaceutically acceptable prodrug or pharmaceutically active metabolites derivatives of formula IV or its corresponding salts, and its pharmaceutical compositions, and methods of using the same, classified in multiple classes and

subclasses. This group may be subjected to further restriction. A single disclosed specie is requested for search purpose.

XVII. Claims 61-71 in part, drawn to nonheterocyclic derivatives of formula V including its salts, and its pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.

XVIII. Claims 61-71 in part, drawn to heterocyclic derivatives of formula V including its salts, and pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.

XIX. Claims 72-78 in part, drawn to method of using compounds embraced by formula V or its salts as described in the said claims. This group may be subjected to further restriction. A single disclosed specie is requested for search purposes.

XX. Claims 61-71 in part, and claims 72-78 drawn to pharmaceutically acceptable prodrug or pharmaceutically active metabolites derivatives of formula V or its corresponding salts, and its pharmaceutical compositions, and methods of using the same, classified in multiple classes and

subclasses. This group may be subjected to further restriction. A single disclosed specie is requested for search purpose.

- XXI. Claims 79-89 in part, drawn to nonheterocyclic derivatives of formula VI including its salts, and its pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.
- XXII. Claims 79-89 in part, drawn to heterocyclic derivatives of formula VI including its salts, and pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.
- XXIII. Claims 90-92 in part, drawn to method of using compounds embraced by formula VI or its salts as described in the said claims. This group may be subjected to further restriction. A single disclosed specie is requested for search purposes.
- XXIV. Claims 79-89 in part, and claims 90-92 drawn to pharmaceutically acceptable prodrug or pharmaceutically active metabolites derivatives of formula VI or its corresponding salts, and its pharmaceutical compositions,

and methods of using the same, classified in multiple classes and subclasses. This group may be subjected to further restriction. A single disclosed specie is requested for search purpose.

XXV. Claims 93-101 in part, drawn to nonheterocyclic derivatives of formula VII including its salts, and its pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.

XXVI. Claims 93-101 in part, drawn to heterocyclic derivatives of formula VII including its salts, and pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.

XXVII. Claims 102-104 in part, drawn to method of using compounds embraced by formula VII or its salts as described in the said claims. This group may be subjected to further restriction. A single disclosed specie is requested for search purposes.

XXVIII. Claims 93-101 in part, and claims 102-104 drawn to pharmaceutically acceptable prodrug or pharmaceutically active metabolites derivatives of

formula VII or its corresponding salts, and its pharmaceutical compositions, and methods of using the same, classified in multiple classes and subclasses. This group may be subjected to further restriction. A single disclosed specie is requested for search purpose.

XXIX. Claims 105-115 in part, drawn to nonheterocyclic derivatives of formula VIII including its salts, and its pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.

XXX. Claims 105-115 in part, drawn to heterocyclic derivatives of formula VIII including its salts, and pharmaceutical compositions, classified in multiple classes and subclasses. A single disclosed specie is requested for search purposes.

XXXI. Claims 116-118 in part, drawn to method of using compounds embraced by formula VIII or its salts as described in the said claims. This group may be subjected to further restriction. A single disclosed specie is requested for search purposes.

XXXII. Claims 105-115 in part, and claims 116-118 drawn to pharmaceutically acceptable prodrug or pharmaceutically active metabolites derivatives of

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formula VIII or its corresponding salts, and its pharmaceutical compositions, and methods of using the same, classified in multiple classes and subclasses. This group may be subjected to further restriction. A single disclosed specie is requested for search purpose.

The inventions are distinct, each from the other because of the following reasons:

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case:

- Inventions I, II, V, VI, IX, X, XIII, XIV, XVII, XVIII, XXI, XXII, XV, XVI, XXIX and XXX are unrelated because they are different inventions since each one of the said groups are drawn to compounds having a particular core per groups-and its corresponding pharmaceutical compositions, and the compounds embraced in each group have its own reactivity, structure and variable groups. Indeed a reference anticipating or suggesting a given group cannot be used to reject any of the others under the meaning of 35 USC 102 or 35 USC 103.
- Inventions III, VII, XV, XIX, XXIII, XXVII and XXXI are unrelated because each one of the said groups are drawn to methods of using different sets of compounds embraced by different groups already shown to be a separate and distinct inventions.
- Inventions IV, VIII, XII, XVI, XX, XXIV, XXVIII and XXXII are unrelated among them and among any other groups. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions because they are drawn to metabolites, or its corresponding salts or prodrugs; methods of using the same or pharmaceutical compositions comprising the same; each of them having a particular chemical structure reactivity and functionality.

- Inventions I, II, V, VI, IX, X, XIII, XIV, XVII, XVIII, XXI, XXII, XV, XVI, XXIX, XXX and inventions III, VII, XV, XIX, XXIII, XXVII and XXXI because are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the diseases that are being treated by the claimed method of use can be treated by another methods no related to the compounds being claim in the instant claims. For instance, Jackson et al, US patent 6635642, teaches a series of methods directed to treat conditions such as pain, wherein the claimed compounds are not required.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for any group is not required any of the others, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hector M Reyes whose telephone number is (571) 272-0691. The examiner can normally be reached on M-F (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rita Desai can be reached on (571) 272 0684. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hector M. Reyes, PhD JD
Reg. # P-54846
AU 1625
July 19, 2004

R. Desai
7/19/2004